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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,971	09/28/2001	Dale R. Schulze	14826 (ETH-1579)	5810

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04/22/2004

Scully, Scott, Murphy, & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

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DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,971

Applicant(s)

SCHULZE, DALE R.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,8,14,16,21,27,34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,5,6, 9, 10-13,15,17-20,22,23,25,26,28-33,35 and 37-40.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3, 7, 8, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Vargas et al. "Vargas" US 6,478,804. Regarding claim 1, Vargas discloses an arrangement comprising a wire (116, fig 20) inherently capable of having one end inserted into a target vessel by puncturing the wall of said vessel and exiting said vessel by puncturing the wall at a spaced location so as to define a region of contact between said vessels, said wiring being inherently capable of puncturing through said walls of said graft vessel upon position of said graft vessel on target vessel. Element 14d, of fig 24 is a means for implanting anastomosis, and element 110 is a means for causing said wire to through the adjoining walls. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
2. Regarding claim 3, the Vargas wire is longitudinally reciprocated. The definition from the specification of longitudinal reciprocated requires the wire to be a cheese cutter. The Vargas wire is inherently capable of cutting cheese.

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3. Regarding claim 7, figure 19 shows an end-to-side anastomosis formation.
4. Regarding claim 8, said wire extends towards the interior of said graft vessel and exits through opposite sidewalls thereof at a spacing from said target vessel, said wire being movable so as to align and contact said vessels with each other (figures 19 and 20).
5. Regarding claim 16, the step of stitching sutures about the joining sides of the vessel (figure 33) is disclosed.
6. Claims 1, 21, 27, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by LeMole US 5,893,369. LeMole discloses an anastomosis system and method comprising: a method for implementing a vascular anastomosis between a graft vessel and a target vessel and subsequently creating a fluid flow passageway between said vessels; said method comprising: inserting a wire (24, figure 6) with one end into said target vessel by puncturing the wall of said vessel (22) and exiting said vessel by puncturing the wall at a spaced location so as to define a region of contact between said vessels (space between both ends of 24); said wire puncturing through the walls of said graft vessel (12) upon positioning of said graft vessel on said target vessel; implementing anastomosis between said vessels adjacent said region of contact between said vessels (the anastomosis is implemented adjacent (or next to) the region); and for causing said wire to cut through the adjoining walls of said vessels within the confines of said region of contact (since the puncturing locations define the region, the wire inherently stays within that region) so as to create said fluid flow passageway between said vessels. The wires are stitched to cause the suture to join the sides of the vessels to abut the graft vessel to the target vessel.

7. Regarding claim 34, the hook-shaped needles are shown in figure 4c. The needles are the same size as the length of the opening between the inserting and exiting punctures in the walls of said vessels.

8. Claims 1 & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup III et al "Northrup" US 5,972,024. Northrup discloses an apparatus for anastomosis as well as a method of using his device. In figure 8, Northrup shows the method of joining two vessels. A wire (20) is disclosed. The wire is capable of puncturing the wall of the vessels. A hook-shaped needle is disclosed. The needle is dimensioned to define the distance between the inserting and exiting punctures in the walls.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole 5893369 in view of Alcamo 3123077. LeMole discloses a wire (24), means for implementing an anastomosis (34), and means for causing the wire to cut through vessels (the small diameter of the wire is said means). The LeMole wire is inherently capable of "having one end inserted... on said target vessel." The LeMole wire is smooth at least as depicted in the figures. Alcamo teaches that roughening the surface of suture wire is advantageous because the roughened surface helps maintain the position of the suture wire. At the time of the invention it would have

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been obvious to one having ordinary skill in the art to roughen the surface of the LeMole wire because Alcamo teaches that roughening the surface of a suture wire helps the suture wire maintain its position.

Response to Arguments

Applicant's arguments filed 2/18/04 have been fully considered but they are not persuasive.

10. Regarding Vargas, Vargas discloses the structural components of the applicant's claims. The Vargas device is also structurally capable of being used as the applicant has recited. As disclosed above, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

11. Regarding LeMole, the applicant's amendment required a reconsideration of the LeMole reference but the LeMole device still anticipates the above claims as described above. Regarding the applicant's argument about the examiner using one element to refer to two distinct elements, There are multiple elements disclosed as element 24 in the LeMole device. Half of them are considered sutures and the other half are considered wires.

12. Regarding Northrup III, the same arguments about intended use apply as discussed in the response to Vargas reference. The applicant is arguing that Northrup III, teaches using his

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device differently than what the applicant has claimed. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Response to Remarks page 10, claim 24: claim 24 is rejoined into the elected claims. The action has included claim 24 with the rejection of claim 4. Claim 34 is not allowable for the reasons discussed supra. The action is made Final because the new limitations of claims 1 and 24 required the examiner to reconsider the LeMole reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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04/06/04


MICHAEL J. MILANO 4/6/04
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